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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,619	08/25/2004	Douglas O. Clary	UCAL-305CON4	4389

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,619	CLARY ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 7-15, in the reply filed on 4/27/07 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on all of the claims together in the present application. This is not found persuasive because Applicant's assertion that there is no search burden is not supported by argument or evidence sufficient to rebut the Examiner's restriction requirement filed 4/5/07, particularly the reasoning provided on pages 3-4. However, the Examiner has reconsidered the species election requirement, and the election of species between trkA, trkB, and trkC (claim 8) is hereby withdrawn and the claims have been examined to their full reasonable scope.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-6 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. The disclosure is objected to because of the following informalities: SEQ ID NOs need to be amended into the specification at page 36, lines 13 and 18 and at page 37, lines 1, 3, 28 and 30.

Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). The specification discloses that normal young (neonatal) healthy rat neurons from one ganglion of the peripheral nervous system (PNS), specifically, neurons only from the superior cervical ganglion, can have their survival in tissue culture stimulated to only about 60% of what their survival would have been if nerve growth factor (NGF) had been used in said tissue culture, if said NGF had not been substituted with a multivalent antibody that binds to the NGF receptor, trkA. In other words, the method of the instant invention substitutes an agonist antibody for NGF *in vitro*, and the agonist antibody does not work as well as NGF (the antibody is 40% less effective than NGF). There are no working examples of the instant method being used to treat any neurological disorder *in vivo*. This is indeed problematic because the nature of the invention is drawn to attempting to treat neurological disorders which are notoriously difficult to treat, such as Alzheimer's

disease (AD). Although there is no prior art of record concerning methods using antibodies directed against trk receptors to treat neurological disorders, there is closely analogous art concerning the failure of NGF to treat neurological disorders, and this art is relevant because the instant disclosure teaches that NGF itself works better that the antibodies of the instant disclosure, and both the instant antibodies and the NGF are producing their therapeutic properties by working through the same receptor system. Olson teaches that a pilot case study of using intraventricular NGF in one AD patient did not result in any meaningful clinical treatment (pages 9-12). Olson writes that "the one conclusion that we feel is warranted, however, is that one should continue with limited carefully monitored clinical trials" (page 10). Therefore, the art teaches that the quantity of experimentation necessary remains quite large, and the instant specification does not provide any more specific guidance or direction that would necessarily limit the large amount of experimentation needed. In fact, the state of the art was well aware of the possibility of using neurotrophic factors to stimulate trk receptors to treat disease at the time of the invention (see Tuszynski et al. (1994), Olson (1993), and Rich et al. (1986)). Despite the passage of 13 to 21 years from the dates of publication of the art cited, the naturally occurring neurotrophins for the trk receptors (NGF, BDNF, NT-3, NT-4/5) have not been developed into any commercially available clinical therapies to treat any of the disorders recited in the instant claims, despite the high skill of those in the medical arts. It is entirely unpredictable, given the instant disclosure, how antibodies that are only 60% as effective as the naturally occurring neurotrophins are going to succeed in a predictable fashion when the neurotrophins themselves appear to be ineffective for

treating any of the diseases recited in the instant claims, which, as recited, require a method of therapy for a neurological disorder in order to be considered enabled. The nature of the art informs us that the *in vitro* methods described in both the art and the instant specification are not predictive of actual therapeutic or clinical outcome.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SG

Stephen Gucker

August 6, 2007

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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